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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,086	08/01/2003	Mark G. Currie	0701.187C	3206

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,086	CURRIE ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/4/04 and 8/1/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/369,828 in view of Carling et al. (WO 93/11773) or Gavin (WO 01/78742).

Copending Application 10/369,828 is drawn to compounds, composition and method of use of compounds of formula I as claimed by the instant invention. The instant application differs from the cited copending Application by the reciting of a composition comprising said compounds and a β_2 adrenergic agonist. However, combination of an anti-inflammatory agent and a β_2 adrenergic agonist is known in the art. For example, each of Carling et al. and Gavin et al. teach a composition comprising an anti-inflammatory agent and a β_2 adrenergic agonist for use in the treatment of

respiratory diseases such as asthma and chronic obstructive pulmonary disease (see both references in its entirety, especially the Abstracts and WO 01/78742, page 4, lines 2-6). Therefore, it would have been obvious to the skilled artisan to combine a β_2 adrenergic agent with the instantly claimed compounds with the reasonable expectation that said combination would be useful as taught by Carling and Gavin.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recites "analogs thereof". However, the present specification lacks description of "analogs" and, thus, does not convey to the skilled artisan in the art at the time of the present application that applicant had possession of the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 5, 8, 10, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite for the following reasons:

(a) Each of claims 2, 5, 8 and 10 is missing a period and, thus, the metes and bound of the claimed invention is indefinite.

(b) Each of claims 14 and 15 recite β_2 adrenergic agonist and "analogs thereof". The present specification lacks definition of said "analogs" and, thus, it is unclear what is encompassed by the instant claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-6 and 13-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allais et al. (US 3,329,570), Csaky (Cutting's Handbook of Pharmacology, pages 351-358), Carling et al. (WO 93/11773) and Gavin (WO 01/78742) in combination.

Allais et al. teach 21-dicyclohexylmethyl carbonate esters of pregnane derivatives such as the 21-dicyclohexylmethyl carbonate ester of 9α-fluoro-16α-hydroxy prednisolone and their prolonged anti-inflammatory action (see the entire article, especially col. 1, lines 26-68; col. 3, lines 58-75). The reference also teaches utilization of the compounds for treatment of disorders such as asthma and emphysema and various formulations thereof (see col. 4, lines 1-28).

Each of Carling et al. and Gavin et al. teach the combination of an anti-inflammatory agent and a β_2 adrenergic agonist in the treatment of respiratory diseases such as asthma and chronic obstructive pulmonary disease (see both references in its entirety, especially the Abstracts and WO 01/78742, page 4, lines 2-6). The references also teach (a) pharmaceutical formulations which are suitable for inhalation (see WO 93/11773, page 6, lines 31-36 and WO 01/78742, page 5, line 25 – page 7, line 17) and (b) the simultaneous, sequential or separate administration of the composition (see for example, WO 93/11773, page 5, line 13 – page 6, line 3 and WO 01/78742, page 5, lines 1-5).

In combination, the prior art makes obvious the combination of the anti-inflammatory agents as taught Allais and β_2 adrenergic agonists in the treatment of respiratory diseases. The motivation to modify the combinations taught by Carling and Gavin by utilization of the anti-inflammatory agents taught by Allais in the treatment of respiratory diseases is based on the teachings by Allais that 21-dicyclohexylmethyl carbonate esters of corticosteroids of the pregnane series have "very favorable, retarded or prolonged anti-inflammatory effect" (see Allais, col. 3, lines 35-39).

Claims 4, 5 and 13 differ from the reference by reciting compounds not exemplified by the reference. However, (a) Allais teaches carbonate esters of pregnane derivatives and (b) Csaky teaches various pregnane derivatives including difluprednate and flucloronide (see pages 351-358). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make the esters of Allias utilizing the pregnane derivatives taught by Csaky with the reasonable expectation that the compounds produced would have similar properties as taught by Allias. The motivation would be based on the desire to make additional anti-inflammatory agents useful as taught by Allais.

Claim 21 further differs from the above-cited references by reciting rhinitis. However, rhinitis is known in the art to be an inflammatory disease of the respiratory system (see Stedman's 27th Edition and Ducoux et al., US 6,642,233, col. 20, lines 7-24). Thus, the utilization of the combination as discussed above in the treatment of rhinitis is prima facie obvious.

Claim 23 further differ from the reference by reciting a specific regimen, i.e., administration within four hours of each other. The determination of treatment regimens is routinely done in the medical art. Thus, the claimed invention is prima facie obvious absence a showing of criticality of the claimed regimen.

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
August 19, 2005